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SPINE DISTRACTION IMPLANT AND METHOD

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Background of the Invention:

Arso's

As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example, with aging comes increases in spinal stenosis (including but not limited to central canal and lateral stenosis), the thickening of the bones which make up the spinal column and facet arthropathy. Spinal stenosis is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by medication and/or surgery. Of course, it is desirable to eliminate the need for major surgery for all individuals and in particular for the elderly.

Accordingly, there needs to be developed procedures and implants for alleviating such condition which are minimally invasive, can be tolerated by the elderly and can be performed preferably on an outpatient basis.

Summary of the Invention:

The present invention is directed to providing a minimally invasive implant and method for alleviating discomfort associated with the spinal column.

The present invention provides for apparatus and method for relieving pain by relieving the pressure and restrictions on the aforementioned blood vessels and nerves. Such alleviation of pressure

is accomplished in the present invention through the use of an implant and method which distract the spinous process of adjacent vertebra in order to alleviate the problems caused by spinal stenosis and facet arthropathy and the like. While the implant and method particularly address the needs of the elderly, the invention can be used with individuals of all ages and sizes where distraction of the spinous process would be beneficial.

In one aspect of the invention, an implant is provided for relieving pain comprising a device positioned between a first spinous process and a second spinous process. The device includes a spinal column extension stop and a spinal column flexion non-inhibitor.

In another aspect of the invention, the implant is positioned between the first spinous process and the second spinous process and includes a distraction wedge that can distract the first and second spinous processes as the implant is positioned between the spinous processes.

In yet another aspect of the present invention, the implant includes a device which is adapted to increasing the volume of the spinal canal and/or the neural foramen as the device is positioned between adjacent spinous processes.

In yet a further aspect of the present invention, a method is presented for relieving pain due to the development of, by way of example only, spinal stenosis and facet arthropathy. The method is comprised of the steps of accessing adjacent first and second spinal processes of the spinal column and distracting the processes a sufficient amount in order to increase the volume of the spinal canal in order to relieve pain. The method further includes implanting a device in order to maintain the amount of distraction required to relieve such pain.

In yet a further aspect of the invention, the method includes implanting a device in order to achieve the desired distraction and to maintain that distraction.

In yet a further aspect of the invention, the implant includes a first portion and a second portion. The portions are urged together in order to achieve the desired distraction.

Other implants and methods within the spirit and scope of the invention can be used to increase the volume of the spinal canal thereby alleviating restrictions on vessels and nerves associated therewith, and pain.

Brief Description of the Figures

Figs. 1 and 2 depict an embodiment of an implant of the invention which is adjustable in order to select the amount of distraction required. Fig. 1 depicts the implant in a more extended configuration than does Fig. 2.

Figs. 3a and 3b depict side and end views of a first forked end of the embodiment of Fig. 1.

Figs. 4a and 4b depict side sectioned and end views of an interbody piece of the implant of Fig. 1.

Figs. 5a and 5b depict side and end views of a second forked end of the embodiment of Fig. 1.

Figs. 6, 7, 8, 9 and 10 depict apparatus and method for another embodiment of the present invention for creating distraction between adjacent spinous processes.

Figs. 11, 12 and 13 depict yet a further embodiment of the invention for creating distraction between adjacent spinous processes.

Figs. 14 and 15 depict a further apparatus and method of an embodiment of the invention for creating distraction.

Figs. 16, 16a, and 17 depict yet another embodiment of the present invention.

Figs. 18, 19 and 20 depict yet a further apparatus and method of the present embodiment.

5 Figs. 21 and 22 depict still a further embodiment of the present invention.

Figs. 23, 24 and 25 depict another embodiment of the present invention.

Figs. 26, 27 and 28 depict another embodiment of the invention.

10 Figs. 29 and 30 depict side elevational views of differently shaped implants of embodiments of the present invention.

Figs. 31, 32 and 33 depict various implant positions of an apparatus of the present invention.

15 Figs. 34 and 35 depict yet another apparatus and method of the present invention.

Figs. 36, 37 and 38 depict three different embodiments of the present invention.

Figs. 39 and 40 depict yet another apparatus and method of an embodiment of the present invention.

20 Figs. 41, 42 and 43 depict yet further embodiments of an apparatus and method of the present invention.

Fig. 44 is still a further embodiment of an implant of the invention.

25 Fig. 45 is yet another depiction of an apparatus and method of the invention.

Figs. 46 and 47 depict still a further apparatus and method of an embodiment of the invention.

Figs. 48, 49, 50 and 51 depict yet a further apparatus and method of the invention.

Figs. 52, 53, 54, 55a and 55b depict another apparatus and method of the invention.

Figs. 56, 57 and 58 depict yet a further apparatus and method of the invention.

5 Figs. 59 and 60 depict still a further embodiment of the invention.

Fig. 61 depict another embodiment of the invention.

Figs. 62 and 63 depict yet another embodiment of the present invention.

10 Figs. 64 and 65 depict still a further embodiment of the present invention.

Fig. 66 depicts another embodiment of the invention.

Figs. 67 and 68 depict yet another embodiment of the present invention.

15 Figs. 69, 70, 71 and 71a depict a further embodiment of the present invention.

Figs. 72 and 73 depict still another embodiment of the invention.

Figs. 74, 75, 76, 77, and 78 depict still other embodiments of the invention.

20 **Detailed Description of the Preferred Embodiment**

Embodiment of Figs. 1-5a, 5b

25 A first embodiment of the invention is shown in Figs. 1-5a, 5b. Implant 20 includes first and second forked ends 22 and 24, each defining a saddle 26, 28 respectively. The forked ends 22, 24 are mated using an interbody piece 30. As can be seen in Figs. 3a, 3b, the first forked end 22 includes a threaded shaft 32 which projects rearwardly from the saddle 26. The threaded shaft 32 fits into the threaded bore 34 (Fig. 4a) of the interbody piece 30.

The second forked end 24 (Figs. 5a, 5b) includes a smooth cylindrical shaft 36 which can fit into the smooth bore 38 of the interbody piece 30.

Fig. 1 shows the implant 20 in a fully extended position, while Fig. 2 shows the implant in an unextended position. In the unextended position, it can be seen that the threaded shaft 32 of the first forked end 22 fits inside the hollow cylindrical shaft 36 of the second forked end 24.

For purposes of implantation between adjacent first and second spinous processes of the spinal column, the implant 20 is configured as shown in Fig. 2. The first and second spinous processes are exposed using appropriate surgical techniques and thereafter, the implant 20 is positioned so that saddle 26 engages the first spinous process, and saddle 28 engages the second spinous process. At this point, the interbody piece 30 can be rotated by placing an appropriate tool or pin into the cross holes 40 and upon rotation, the saddle 26 is moved relative to the saddle 28. Such rotation spreads apart or distracts the spinous processes with the resultant and beneficial effect of enlarging the volume of the spinal canal in order to alleviate any restrictions on blood vessels and nerves.

It is noted that this implant as well as the several other implants described herein act as an extension stop. That means that as the back is bent backwardly and thereby placed in extension the spacing between adjacent spinous processes cannot be reduced to a distance less than the distance between the lowest point of saddle 26 and the lowest point of saddle 28. This implant, however, does not inhibit or in any way limit the flexion of the spinal column, wherein the spinal column is bent forward.

Preferably, such a device provides for distraction in the range of about 5 millimeters to about 15 millimeters. However, devices which can distract up to and above 22 millimeters may be used depending on the characteristics of the individual patient.

5 With all the ligaments (such as the supraspinous ligament) and tissues associated with the spinous processes left intact, the implant 20 can be implanted essentially floating in position in order to gain the benefits of the aforementioned extension stop and flexion non-inhibitor. If desired, one of the saddles 26 can be laterally pinned with pin 29 to one of the spinous processes and the other saddle can be loosely associated with the other spinous processes by using a tether 31 which either pierces or surrounds the other spinous process and then is attached to the saddle in order to position the saddle relative to the spinous process. Alternatively, both saddles can be loosely tethered to the adjacent spinous process in order to allow the saddles to move relative to the spinous processes.

10 The shape of the saddles, being concave, gives the advantage of distributing the forces between the saddle and the respective spinous process. This ensures that the bone is not resorbed due to the placement of the implant 20 and that the structural integrity of the bone is maintained.

20 The implant 20 in this embodiment can be made of a number of materials, including but not limited to, stainless steel, titanium, ceramics, plastics, elastics, composite materials or any combination of the above. In addition, the modulus of elasticity of the implant can be matched to that of bone, so that the implant 20 is not too rigid. The flexibility of the implant can further be enhanced by providing additional apertures or perforations throughout the implant in addition to the holes 40 which also have the above stated purpose of allowing the interbody

piece 30 to be rotated in order to expand the distance between the saddle 26, 28.

5 In the present embodiment, it is understood that the spinous processes can be accessed and distracted initially using appropriate instrumentation, and that the implant 20 can be inserted and adjusted in order to maintain and achieve the desired distraction. Alternatively, the spinous process can be accessed and the implant 20 appropriately positioned. Once positioned, the length of the implant can be adjusted in order to distract the spinous processes or extend the distraction of already distracted spinous processes. Thus, the implant can be used to create a distraction or to maintain a distraction which has already been created.

10 The placement of implants such as implant 20 relative to the spinous process will be discussed hereinbelow with other embodiments. However, it is to be noted that ideally, the implant 20 would be placed close to the instantaneous axis of rotation of the spinal column so that the forces placed on the implant 20 and the forces that the implant 20 places on the spinal column are minimized.

15 Further, it is noted that during the actual process of installing or implanting the implant 20, that the method uses the approach of extending the length of the implant 20 a first amount and then allowing the spine to creep or adjust to this distraction. Thereafter, implant 20 would be lengthened another amount, followed by a period where the spine is allowed to creep or adjust to this new level of distraction. This process could be repeated until the desired amount of distraction has been accomplished. This same method can be used with insertion tools prior to the installation of an implant. The tools can be used to obtain the desired distraction using a series of spinal distraction and spine creep periods before an implant is installed.

Embodiment of Figs. 6, 7, 8, 9 and 10

5 The embodiment of the invention shown in the above Figs. 6, 7, 8, 9 and 10 includes distraction or spreader tool 50 which has first and second arms 52, 54. Arms 52, 54 are pivotal about pivot point 56 and releaseable from pivot point 56 in order to effect the implantation of implant 58. As can be seen in Fig. 6, in cross-section, the arms 52, 54 are somewhat concave in order to cradle and securely hold the first spinous process 60 relative to arm 52 and the second spinous process 62 relative to arm 54. The distraction tool 50 can be inserted through a small incision in the back of the patient in order to address the space between the first spinous process 60 and the second spinous process 62. Once the tool 50 is appropriately positioned, the arms 52, 54 can be spread apart in order to distract the spinous processes. After this has occurred, an implant 58 as shown in Figs. 8 and 9, or of a design shown in other of the embodiments of this invention, can be urged between the arms 52, 54 and into position between the spinous processes. After this occurs, the arms 52, 54 can be withdrawn from the spinous processes leaving the implant 58 in place. The implant 58 is urged into place using a tool 64 which can be secured to the implant 58 through a threaded bore 66 in the back of the implant. As can be seen in Fig. 10, the implant 58 includes saddles 68 and 70 which cradle the upper and lower spinous processes 60, 62 in much the same manner as the above first embodiment and also in much the same manner as the individual arms of the tool 50. The saddles as described above tend to distribute the load between the implant and the spinous processes and also assure that the spinous process is stably seated at the lowest point of the respective saddles.

Embodiment of Figs. 11, 12 and 13

Another embodiment of the apparatus and method of the invention is shown in Figs. 11, 12 and 13. In this embodiment, the spreader or distraction tool 80 includes first and second arms 82, 84 which are permanently pivoted at pivot point 86. The arms include L-shaped ends 88, 90. Through a small incision, the L-shaped ends 88, 90 can be inserted between the first and second spinous processes 92, 94. Once positioned, the arms 82, 84 can be spread apart in order to distract the spinous processes. The implant 96 can then be urged between the spinous processes in order to maintain the distraction. It is noted that implant 96 includes wedged surfaces or ramps 98, 100. As the implant 96 is being urged between the spinous processes, the ramps further cause the spinous processes to be distracted. Once the implant 96 is fully implanted, the full distraction is maintained by the planar surfaces 99, 101 located rearwardly of the ramps. It is to be understood that the cross-section of the implant 96 can be similar to that shown for implant 58 or similar to other implants in order to gain the advantages of load distribution and stability.

Embodiments of Figs. 14, 15, 16, 16a, and 17

In Figs. 14 and 15, yet another embodiment of the invention is depicted. In this embodiment, the implant 110 includes first and second conically shaped members 112, 114. Member 112 includes a male snap connector 116 and member 114 includes a female snap connector 118. With male snap connector 116 urged into female snap connector 118, the first member 112 is locked to the second member 114. In this embodiment, a distraction or spreader tool 80 could be used. Once the spinous process has been spread apart, an implantation tool 120 can be used to position and snap together the implant 110. The first member

112 of implant 110 is mounted on one arm and second member 114 is mounted on the other arm of tool 120. The member 112, 114 are placed on opposite sides of the space between adjacent spinous processes. The members 112, 114 are urged together so that the implant 110 is locked in place between the spinous processes as shown in Fig. 15. It is to be noted that the implant 110 can also be made more self-distracting by causing the cylindrical surface 122 to be more conical, much as surface 124 is conical, in order to hold implant 110 in place relative to the spinous processes and also to create additional distraction.

An alternative embodiment of the implant can be seen in Figs. 16 and 17. This implant 130 includes first and second members 132, 134. In this particular embodiment, the implants are held together using a screw (not shown) which is inserted through countersunk bore 136 and engages a threaded bore 138 of the second member 134. Surfaces 139 are flattened (Fig. 17) in order to carry and spread the load applied thereto by the spinous processes.

The embodiment of implant 130 is not circular in overall outside appearance, as is the embodiment 110 of Figs. 14 and 15. In particular, with respect to the embodiment of implant 130 of Figs. 16 and 17, this embodiment is truncated so that the lateral side 140, 142 are flattened with the upper and lower sides 144, 146 being elongated in order to capture and create a saddle for the upper and lower spinous processes. The upper and lower sides, 144, 146 are rounded to provide a more anatomical implant which is compatible with the spinous processes.

If it is desired, and in order to assure that the first member 132 and the second member 134 are aligned, key 148 and keyway 150 are designed to mate in a particular manner. Key 148 includes at least one

flattened surface, such as flattened surface 152, which mates to an appropriately flattened surface 154 of the keyway 150. In this manner, the first member is appropriately mated to the second member in order to form appropriate upper and lower saddles holding the implant 130 relative to the upper and lower spinous processes.

Fig. 16a depicts second member 134 in combination with a rounded nose lead-in plug 135. Lead-in plug 135 includes a bore 137 which can fit snugly over key 148. In this configuration, the lead-in plug 135 can be used to assist in the placement of the second member 134 between spinous processes. Once the second member 134 is appropriately positioned, the lead-in plug 135 can be removed. It is to be understood that the lead-in plug 135 can have other shapes such as pyramids and cones to assist in urging apart the spinous processes and soft tissues in order to position the second member 134.

Embodiment of Figs. 18, 19 and 20

The implant 330 as shown in Fig. 18 is comprised of first and second mating wedges 332 and 334. In order to implant these wedges 332, 334, the spinous processes are accessed from both sides and then a tool is used to push the wedges towards each other. As the wedges are urged towards each other, the wedges move relative to each other so that the combined dimension of the implant 330 located between the upper and lower spinous processes 336, 338 (Fig. 20), increases, thereby distracting the spinous processes. It is noted that the wedges 332, 334 include saddle 340, 342, which receiving the spinous processes 336, 338. These saddles have the advantages as described hereinabove.

The first or second wedges 332, 334 have a mating arrangement which includes a channel 344 and a projection of 346 which can be

5 urged into the channel in order to lock the wedges 332, 334 together. The channel 334 is undercut in order to keep the projection from separating therefrom. Further, as in other devices described herein, a detent can be located in one of the channel and the projection, with a complimentary recess in the other of the channel and the projection. Once these two snap together, the wedges are prevented from sliding relative to the other in the channel 344.

10 While the above embodiment was described with respect to wedges, the wedges could also have been designed substantially as cones with all the same features and advantages.

Embodiments of Figs. 21 and 22

15 The implant 370 is comprised of first and second distraction cone 372, 374. These cones are made of a flexible material. The cones are positioned on either side of the spinous processes 376, 378 as shown in Fig. 21. Using appropriate tool as shown hereinabove, the distraction cones 372, 374 are urged together. As they are urged together, the cones distract the spinous processes as shown in Fig. 22. Once this has occurred, an appropriate screw or other type of fastening mechanism 380 can be used to maintain the position of the distraction cones 372, 374. The advantage of this arrangement is that the implant 370 is self-distracting and also that the implant, being flexible, molds about the spinous processes as shown in Fig. 22.

Embodiments of Fig. 23, 24 and 25

25 In Figs. 23 and 24, another embodiment of the implant 170 is depicted. This implant is guided in place using an L-shaped guide 172 which can have a concave cross-section such as the cross-section 52 of retraction tool 50 in Fig. 6 in order to cradle and guide the implant

170 in position. Preferably a small incision would be made into the back of the patient and the L-shaped guide tool 172 inserted between the adjacent spinous processes. The implant 170 would be mounted on the end of insertion tool 174 and urged into position between the spinous processes. The act of urging the implant into position could cause the spinous processes to be further distracted if that is required. Prior to the insertion of the L-shaped guide tool 172, a distraction tool such as shown in Fig. 13 could be used to initially distract the spinous processes.

Implant 170 can be made of a deformable material so that it can be urged into place and so that it can somewhat conform to the shape of the upper and lower spinous processes. This deformable material would be preferably an elastic material. The advantage of such a material would be that the load forces between the implant and the spinous processes would be distributed over a much broader surface area. Further, the implant would mold itself to an irregular spinous process shape in order to locate the implant relative to spinous processes.

With respect to Fig. 25, this implant 176 can be inserted over a guide wire, guide tool or stylet 178. Initially, the guide wire 178 is positioned through a small incision to the back of the patient to a position between the adjacent spinous processes. After this has occurred, the implant is threaded over the guide wire 178 and urged into position between the spinous processes. This urging can further distract the spinous processes if further distraction is required. Once the implant is in place, the guide tool 178 is removed and the incision closed. The insertion tools of Figs. 23 and 24 can also be used if desired.

Embodiment of Figs. 26, 27 and 28

The embodiment shown in Figs. 26, 27 and 28 uses an implant similar to that depicted in Figs. 8 and 9 with different insertion tools. As can be seen in Fig. 26, an L-shaped distraction tool 190 is similar to L-shaped distraction tool 80 (Fig. 12), is used to distract the first and second spinous processes 192, 194. After this has occurred, an insertion tool 196 is placed between the spinous processes 192, 194. Insertion tool 196 includes a handle 198 to which is mounted a square-shaped ring 200.

The distraction tool 190 can be inserted through a small incision in the back in order to spread apart the spinous processes. Through the same incision which has been slightly enlarged laterally, an upper end 202 of ring 200 can be initially inserted followed by the remainder of the ring 200. Once the ring is inserted, the ring can be rotated slightly by moving handle 198 downwardly in order to further wedge the spinous processes apart. Once this has been accomplished, an implant such as implant 204 can be inserted through the ring and properly positioned using implant handle 206. Thereafter, the implant handle 206 and the insertion tool 196 can be removed.

Embodiments of Figs. 29, 30, 31, 32 and 33

As can be seen in Figs. 29 and 30, the implants 210, 212, can have different shapes when viewed from the side. These implants are similar to the above-referenced implants 58 (Fig. 8) and 204 (Fig. 28). These implants have cross-sections similar to that shown in Fig. 10 which includes saddles in order to receive and hold the adjacent spinous processes.

As can be seen in Figs. 31, 32 and 33, these implants can be placed in different positions with respect to the spinous process 214.

Preferably as shown in Fig. 33, the implant 210 is placed closest to the lamina 216. Being so positioned, the implant 210 is close to the instantaneous axis of rotation 218 of the spinal column, and the implant would experience least forces caused by movement of the spine. Thus, theoretically, this is the optimal location for the implant.

As can be seen in Figs. 31 and 32, the implant can be placed midway along the spinous process (Fig. 32) and towards the posterior aspect of the spinous process (Fig. 31). As positioned shown in Fig. 31, the greatest force would be placed on the implant 210 due to a combination of compression and extension of the spinal column.

Embodiment of Figs. 34 and 35

Another embodiment of the invention is shown in Figs. 34 and 35. In these figures, implant 220 is comprised of a plurality of individual leaves 222 which are substantially V-shaped. The leaves include interlocking indentations or detents 224. That is, each leaf includes an indentation with a corresponding protrusion such that a protrusion of one leaf mates with an indentation of an adjacent leaf. Also associated with this embodiment is an insertion tool 226 which has a blunt end 228 which conforms to the shape of an individual leaf 222. For insertion of this implant into the space between the spinous processes as shown in Fig. 29, the insertion tool 226 first insert a single leaf 220. After that has occurred, the insertion tool then inserts a second leaf with the protrusion 224 of the second leaf snapping into corresponding indentation made by the protrusion 224 of the first leaf. This process would reoccur with third and subsequent leaves until the appropriate spacing between the spinous processes was built up. As can be seen in Fig. 29, the lateral edges 229 of the individual leaves

222 are slightly curved upwardly in order to form a saddle for receiving the upper and lower spinous processes.

Embodiments of Figs. 36, 37 and 38

5 The embodiments of Figs. 36, 37 and 38 which include implants 230, 232, and 234 respectively, are designed in such a manner so the implant locks itself into position once it is properly positioned between the spinous processes. Implant 220 is essentially a series of truncated cones and includes a plurality of ever expanding steps 236. These steps are formed by the conical bodies starting with the nose body 238 followed there behind by conical body 240. Essentially, the implant 234 looks like a fir tree placed on its side.

10 The implant 230 is inserted laterally throughout the opening between upper and lower spinous processes. The first body 238 causes the initial distraction. Each successive conical body distracts the spinous processes a further incremental amount. When the desired distraction has been reached, the spinous processes are locked into position by steps 236. At this point, if desired, the initial nose body 238 of the implant and other bodies 240 can be broken, snapped or sawed off if desired in order to minimize the size of the implant 230. In order for a portion of the implant 230 to be broken or snapped off, the intersection between bodies such as body 238 and 240, which is intersection line 242, would be somewhat weakened with the appropriate removal of material. It is noted that only the intersection lines of the initial conical bodies need to be so weakened. Thus, intersection line 244 between the bodies which remain between the spinous processes would not need to be weaker, as there would be no intention that the implant would be broken off at this point.

Fig. 37 shows implant 232 positioned between upper and lower spinous processes. This implant is wedge-shaped or triangular shaped in cross-sectioned and includes bore pluralities 245 and 246. Through these bores can be placed locking pins 248 and 250. The triangular or wedged-shaped implant can be urged laterally between and thus distract the upper and lower spinous processes. Once the appropriate distraction is reached, pins 248, 250 can be inserted through the appropriate bores of the bore pluralities 245 and 246 in order to lock the spinous processes in a V-shaped valley formed by pins 248, 250 on the one hand and the ramped surface 233, 235 on the other hand.

Turning to Fig. 38, the implant 234 has a triangular-shaped or wedge-shaped body similar to that shown in Fig. 32. In this embodiment, tab 252, 254 are pivotally mounted to the triangular shaped body 234. Once the implant 234 is appropriately positioned in order to distract the spinous processes to the desired amount, the tabs 252, 254 rotate into position in order to hold the implant 234 in the appropriate position.

Embodiment of Figs. 39 and 40

In the embodiment of Figs. 39 and 40, cannula 258 is inserted through a small incision to a position between upper and lower spinous processes. Once the cannula is properly inserted, an implant 260 is pushed through the cannula 258 using an insertion tool 262. The implant 260 includes a plurality of ribs or indentation 264 that assist in positioning the implant 260 relative to the upper and lower spinal processes. Once the implant 260 is in position, the cannula 258 is withdrawn so that the implant 260 comes in contact with and wedges between the spinous processes. The cannula 258 is somewhat conical in shape with the nose end 266 being somewhat smaller than the distal

end 268 in order to effect the insertion of the cannula into the space between the spinous processes.

Further, a plurality of cannula can be used instead of one, with each cannula being slightly bigger than one before. In the method of the invention, the first smaller cannula would be inserted followed by successively larger cannula being placed over the previous smaller cannula. The smaller cannula would then be withdrawn from the center of the larger cannula. Once the largest cannula is in place, and the opening of the skin accordingly expanded, the implant, which is accommodated by only the larger cannula, is inserted through the larger cannula and into position.

Embodiments of Figs. 41, 42 and 43

The precurved implant 270 in Figs. 41 and 42, and precurved implant 272 in Fig. 43 have common introduction techniques which includes a guide wire, guide tool, or stylet 274. For both embodiments, the guide wire 274 is appropriately positioned through the skin of the patient and into the space between the spinous processes. After this is accomplished, the implant is directed over the guide wire and into position between the spinous processes. The precurved nature of the implant assist in (1) positioning the implant through a first small incision in the patient's skin on one side of the space between two spinous processes and (2) guiding the implant toward a second small incision in the patient's skin on the other side of the space between the two spinous processes. With respect to the implant 270, the implant includes a conical introduction nose 276 and a distal portion 278. As the nose 276 is inserted between the spinous processes, this causes distraction of the spinous processes. Break lines 280, 282 are established at opposite sides of the implant 270. Once the implant is

properly positioned over the guide wire between the spinous processes, the nose portion 276 and the distal portion 278 can be broken off along the break lines, through the above two incisions, in order to leave the implant 270 in position.

5 Although only two break lines 280, 282 are depicted, multiple break lines can be provided on implant 270 so that the implant can continue to be fed over the guide wire 278 until the appropriate width of the implant 270 creates the desired amount of distraction. As described hereinabove, the break lines can be created by perforating or otherwise weakening the implant 270 so that the appropriate portions
10 can be snapped or sawed off.

 With respect to the precurved implant 272, this implant is similar in design to the implant 230 shown in Fig. 36. This implant 272 in Fig. 47, however, is precurved and inserted over a guide wire 274 to a position between the spinous processes. As with implant 230 in Fig. 43, once the appropriate level of this distraction has been reached and if desired, sections of the implant 272 can be broken, snapped or sawed off as described hereinabove in order to leave a portion of the implant wedged between the upper and lower spinous processes.
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Embodiment of Fig. 44

20 A further embodiment of the invention is shown in Fig. 44. This embodiment includes a combination insertion tool and implant 290. The insertion tool and implant 290 is in the shape of a ring which is hinged at point 292. The ring is formed by a first elongated and conically shaped member 294 and a second elongated and conically shaped member 296. Members 294 and 296 terminate in points and through the use of hinge 292 are aligned and meet. Through similar incisions on both sides of the spinous processes, first member and second member
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are inserted through the skins of the patient and are mated together between the spinous processes. After this has occurred, the implant 290 is rotated, for example clockwise, so that increasingly widening portions of the first member 292 are used to distract the first and second spinous processes. When the appropriate level of distraction has occurred, the remainder of the ring before and after the section which is located between the spinous processes can be broken off as taught hereinabove in order to maintain the desired distraction. Alternatively, with a small enough ring, the entire ring can be left in place with the spinous processes distracted.

Embodiment of Fig. 45

In Fig. 45, the implant 300 is comprised of a plurality of rods or stylets 302 which are inserted between the upper and lower spinous processes. The rods are designed much as described hereinabove so that they may be broken, snapped or cut off. Once these are inserted and the appropriate distraction has been reached, the stylets are broken off and a segment of each stylet remains in order to maintain distraction of the spinous process.

Embodiment of Figs. 46 and 47

Implant 310 of Figs. 46 and 47 is comprised of a shape memory material which coils upon being released. The material is straightened out in a delivery tool 312. The delivery tool is in position between upper and lower spinous processes 314, 316. The material is then pushed through the delivery tool. As it is released from the delivery end 318 of the delivery tool, the material coils, distracting the spinous processes to the desired amount. Once this distraction has been achieved, the material is cut and the delivery tool removed.

Embodiments of Figs. 48, 49, 50 and 51

As can be seen in Fig. 48, the implant 320 is delivered between upper and lower spinous processes 322 and 324, by delivery tool 326. Once the implant 320 is in place between the spinous processes, the delivery tool is given a 90° twist so that the implant goes from the orientation as shown in Fig. 49, with longest dimension substantially perpendicular to the spinous processes, to the orientation shown in Fig. 50 where the longest dimension is in line with and parallel to the spinous processes. This rotation causes the desired distraction between the spinous processes. Implant 320 includes opposed recesses 321 and 323 located at the ends thereof. Rotation of the implant 320 causes the spinous processes to become lodged in these recesses.

Alternatively, the insertion tool 326 can be used to insert multiple implants 320, 321 into the space between the spinous processes 322, 324 (Fig. 51). Multiple implants 320, 321 can be inserted until the appropriate amount of distraction is built up. It is to be understood in this situation that one implant would lock to another implant by use of, for example, a channel arrangement wherein a projection from one of the implants would be received into and locked into a channel of the other implant. Such a channel arrangement is depicted with respect to the other embodiment.

Embodiment of Figs. 52, 53, 54, 55a and 55b

The embodiment of Figs. 52 through 55b is comprised of a fluid-filled dynamic distraction implant 350. This implant includes a membrane 352 which is placed over pre-bent insertion rod 354 and then inserted through an incision on one side of the spinous process 356. The bent insertion rod, with the implant 350 thereover, is guided between appropriate spinous processes. After this occurs, the insertion

rod 354 is removed leaving the flexible implant in place. The implant 350 is then connected to a source of fluid (gas, liquid, gel and the like) and the fluid is forced into the implant causing it to expand as shown in Fig. 54, distracting the spinal processes to the desired amount. Once the desired amount of distraction has occurred, the implant 350 is closed off as is shown in Fig. 55a. The implant 350 being flexible, can mold to the spinous processes which may be of irregular shape, thus assuring positioning. Further, implant 350 acts as a shock absorber, damping forces and stresses between the implant and the spinous processes.

A variety of materials can be used to make the implant and the fluid which is forced into the implant. By way of example only, viscoelastic substances such as methylcellulose, or hyaluronic acid can be used to fill the implant. Further, materials which are initially a fluid, but later solidify, can be inserted in order to cause the necessary distraction. As the materials solidify, they mold into a custom shape about the spinous processes and accordingly are held in position at least with respect to one of two adjacent spinous processes. Thus, it can be appreciated that using this embodiment and appropriate insertion tools the implant can be formed about one spinous process in such a manner that the implant stays positioned with respect to that spinous process (Fig. 55b). With such an embodiment, a single implant can be used as an extension stop for spinous process located on either side, without restricting flexion of the spinal column.

It is to be understood that many of the other implants disclosed herein can be modified so that they receive a fluid in order to establish and maintain a desired distraction much in the manner as implant 350 receives a fluid.

Embodiment of Figs. 56, 57 and 58

5 The implant 360 as shown in Fig. 56 is comprised of a shape
memory material such as a plastic or a metal. A curved introductory
tool 362 is positioned between the appropriate spinous processes as
described hereinabove. Once this has occurred, bore 364 of the implant
is received over the tool. This act can cause the implant to straighten
out. The implant is then urged into position and thereby distracts the
spinous processes. When this has occurred, the insertion tool 362 is
removed, allowing the implant to assume its pre-straightened
10 configuration and is thereby secured about one of the spinous
processes. Such an arrangement allows for an implant that is an
extension stop and does not inhibit flexion of the spinous column.
Alternatively, the implant can be temperature sensitive. That is to say
that the implant would be more straightened initially, but become more
15 curved when it was warmed by the temperature of the patient's body.

Embodiments of Figs. 59 and 60

20 In this embodiment, the implant 380 is comprised of a plurality of
interlocking leaves 382. Initially, a first leaf is positioned between
opposed spinous processes 384, 386. Then subsequently, leafs 382
are interposed between the spinous processes until the desired
distraction has been built up. The leaves are somewhat spring-like in
order to absorb the shock and can somewhat conform to the spinous
processes.

Embodiment of Fig. 61

25 The implant 390 of Fig. 61 includes the placement of shields 392,
394 over adjacent spinous processes 396, 398. The shields are used
to prevent damage to the spinous processes. These shields include

apertures which receives a self-tapping screw 400, 402. In practice, the shields are affixed to the spinous processes and the spinous processes are distracted in the appropriate amount. Once this has occurred, a rod 404 is used to hold the distracted position by being screwed into each of the spinous processes through the aperture in the shields using the screws as depicted in Fig. 61.

Embodiment of Figs. 62 and 63

Implant 410 of Figs. 62, 63 is comprised of first and second members 412, 414 which can be mated together using an appropriate screw and threaded bore arrangement to form the implant 410. Main member 412 and mating member 414 form implant 410. Accordingly, the implant 410 would have a plurality of members 414 for use with a standardized first member 412. Figs. 62 and 64 show different types of mating members 414. In Fig. 62, the mating member 414 includes projections 416 and 418 which act like shims. These projections are used to project into the space of saddles 420, 422 of the first member 412. These projections 416, 418 can be of varying lengths in order to accommodate different sizes of spinous processes. A groove 424 is placed between the projections 416, 418 and mates with an extension 426 of the first member 412.

As shown in Fig. 63, the projections of the embodiment shown in Fig. 62 are removed and recesses 428, 430 are substituted therefor. These recesses expand the area of the saddles 420, 422 in order to accommodate larger spinous processes.

Embodiment of Figs. 64, 65 and 66

The embodiments of Figs. 64, 65 and 66 are similar in design and concept to the embodiment of Figs. 62 and 63. In Fig. 64, the implant

500 includes the first and second members 502, 504. These members can be secured together with appropriate screws or other fastening means as taught in other embodiments. Implant 500 includes first and second saddles 506, 508 which are formed between the ends of first and second members 502, 504. These saddles 506, 508 are used to receive and cradle the adjacent spinous processes. As can be seen in Fig. 64, each saddle 506, 508 is defined by a single projection or leg 510, 512, which extends from the appropriate first and second members 502, 504. Unlike the embodiment found in Figs. 62 and 63, each of the saddles is defined by only a single leg as the ligaments and other tissues associated with the spinous processes can be used to ensure that the implant is held in an appropriate position. With the configuration of Fig. 64, it is easier to position the implant relative to the spinous processes as each saddle is defined by only a single leg and thus the first and second members can be more easily worked into position between the various tissues.

In the embodiment of Fig. 65, the implant 520 is comprised of a single piece having saddles 522 and 524. The saddles are defined by a single leg 526, 528 respectively. In order for this implant 520 to be positioned between the spinous processes, an incision is made between lateral sides of adjacent spinous processes. The single leg 526 is directed through the incision to a position adjacent to an opposite lateral side of the spinous process with the spinous process cradled in the saddle 522. The spinous processes are then urged apart until saddle 524 can be pivoted into position into engagement with the other spinous process in order to maintain the distraction between the two adjacent spinous processes.

The embodiment of Fig. 66 is similar to that of Fig. 65 with an implant 530 and first and second saddles 532 and 534. Associated

with each saddle is a tether 536, 538 respectively. The tethers are made of flexible materials known in the trade and industry and are positioned through bores in the implant 530. Once appropriately positioned, the tethers can be tied off. It is to be understood that the tethers are not meant to be used to immobilize one spinous process relative to the other, but are used to guide motion of the spinous processes relative to each other so that the implant 530 can be used as an extension stop and a flexion non-inhibitor. In other words, the saddles 532, 534 are used to stop spinal column backward bending and extension. However, the tethers do not inhibit forward bending and spinal column flexion.

Embodiments of Figs. 67, 68

The implant 550 is Z-shaped and includes a central body 552 and first and second arms 554, 556, extending in opposite directions therefrom. The central body 552 of the implant 550 includes first and second saddles 558 and 560. The first and second saddles 558 and 560 would receive upper and lower spinous processes 562, 568. The arms 554, 556 are accordingly located adjacent the distal end 566 (Fig. 68) of the central body 552. The first and second arms 554, 556, act to inhibit forward movement, migration or slippage of the implant 550 toward the spinal canal and keep the implant in place relative to the first and second spinal processes. This prevents the implant from pressing down on the ligamentum flavum and the dura. In a preferred embodiment, the central body would have a height of about 10mm with each of the arms 554, 556 have a height of also about 10mm. Depending on the patient, the height of the body could vary from about less than 10 mm to about greater than 24mm. As can be seen in Figs. 67 and 68, the first and second arms 554, 556 are additionally

contoured in order to accept the upper and lower spinous processes 556, 558. In particular, the arms 554, 556 as can be seen with respect to arm 554 have a slightly outwardly bowed portion 568 (Fig. 68) with a distal end 570 which is slightly inwardly bowed. This configuration allows the arm to fit about the spinous process with the distal end 570 somewhat urged against the spinous process in order to guide the motion of the spinous process relative to the implant. These arms 554, 556 could if desired to be made more flexible than the central body 552 by making arms 554, 556 thin and/or with perforations, and/or other material different than that of the central body 550. As with the last embodiment, this embodiment can be urged into position between adjacent spinous processes by directing an arm into a lateral incision so that the central body 552 can be finally positioned between spinous processes.

Embodiment of Figs. 69, 70, 71 and 71a

Figs. 69, 70 and 71 are perspective front, end, and side views of implant 580 of the invention. This implant includes a central body 582 which has first and second saddles 584, 586 for receiving adjacent spinous processes. Additionally, the implant 580 includes first and second arms 588 and 590. The arms, as with the past embodiment, prevent forward migration or slippage of the implant toward the spinal canal. First arm 588 projects outwardly from the first saddle 584 and second arm 590 projects outwardly from the second saddle 586. In a preferred embodiment, the first arm 588 is located adjacent to the distal end 600 of the central body 582 and proceeds only partly along the length of the central body 582. The first arm 588 is substantially perpendicular to the central body as shown in Fig. 70. Further, the first arm 588, as well as the second arm 590, is anatomically rounded.

The second arm 590, projecting from second saddle 586, is located somewhat rearward of the distal end 600, and extends partially along the length of the central body 582. The second arm 590 projects at a compound angle from the central body 582. As can be seen in Figs. 70 and 71, the second arm 590 is shown to be at about an angle of 45° from the saddle 586 (Fig. 70). Additionally, the second arm 590 is at an angle of about 45° relative to the length of the central body 580 as shown in Fig. 71. It is to be understood that other compound angles are within the spirit and scope of the invention as claimed.

In a preferred embodiment, the first and second arms 588, 590 have a length which is about the same as the width of the central body 582. Preferably, the length of each arm is about 10mm and the width of the central body is about 10mm. However, the bodies with the widths of 24mm and greater are within the spirit and scope of the invention, along with first and second arms ranging from about 10mm to greater than about 24mm. Further, it is contemplated that the embodiment could include a central body having a width of about or greater than 24mm with arms being at about 10mm.

It is to be understood that the embodiment of Figs. 69, 70 and 71 as well as the embodiment of Figs. 67 and 68 are designed to preferably be positioned between the L4-L5 and the L5-S1 vertebral pairs. The embodiment of Figs. 69, 70, 71 is particularly designed for the L5-S1 position with the arms being designed to conform to the sloping surfaces found therebetween. The first and second arms are thus contoured so that they lie flat against the lamina of the vertebra which has a slight angle.

The embodiment of Fig. 69, 70, and 71 as with the embodiment of Figs. 67 and 68 is Z-shaped in configuration so that it may be inserted from one lateral side to a position between adjacent spinous

processes. A first arm, followed by the central body, is guided through the space between the spinous processes. Such an arrangement only requires that a incision on one side of the spinous process be made in order to successfully implant the device between the two spinous processes.

The implant 610 of Fig. 71a is similar to that immediately above with the first arm 612 located on the same side of the implant as the second arm 614. The first and second saddle 616, 618 are slightly modified in that distal portion 620, 622 are somewhat flattened from the normal saddle shape in order to allow the implant to be positioned between the spinous processes from one side. Once in position, the ligaments and tissues associated with the spinous processes would hold the implant into position. Tethers also could be used if desired.

Embodiment of Figs. 72, 73

Implant 630 is also designed so that it can be inserted from one side of adjacent spinous processes. This insert 630 includes a central body 632 with the first and second arms 634, 636 extending on either side thereof. As can be seen in Fig. 72, a plunger 638 is positioned to extend from an end of the central body 632. As shown in Fig. 72, the plunger 638 is fully extended and as shown in Fig. 73, the plunger 638 is received within the central body 632 of the implant 630. With the plunger received into the implant 632, the third and fourth arms or hooks 640, 642 can extend outwardly from the central body 632. The third and fourth arms or hooks 640, 642 can be comprised of a variety of materials, such as for example, shape memory metal materials or materials which have a springy quality.

For purposes of positioning the implant 630 between adjacent spinous processes, the plunger 638 is pulled outwardly as shown in Fig.

72. The central body 632 is then positioned between adjacent spinous processes and the plunger 638 is allowed to move to the position of Fig. 73 so that the third and fourth arms 640, 642 can project outwardly from the central body 632 in order to hold the implant 630 in position between the spinous processes.

Plunger 638 can be spring biased to the position as shown in Fig. 73 or can include detents or other mechanisms which lock it into that position. Further, the third and fourth arms themselves, as deployed, can keep the plunger in the position as shown in Fig. 73.

Embodiments of Figs. 74, 75, 76, 77, and 78

Other embodiments of the invention are shown in Figs. 74 through 78. Figs. 74, 75 and 76 disclose implant 700. Implant 700 is particularly suited for implantation between the L4-L5 and L5-S1 vertebra. As can be seen in Fig. 74, the implant 700 includes a central body 702 which has a bore 704 provided therein. Bore 704 is used in order to adjust the modulus of elasticity of the implant so that it is preferably approximately two times the anatomical load placed on the vertebra in extension. In other words, the implant 700 is approximately two times stiffer than the normal load placed on the implant. Such an arrangement is made in order to ensure that the implant is somewhat flexible in order to reduce potential resorption of the bone adjacent to the implant. Other modulus values can be used and be within the spirit of the invention.

Implant 700 includes first and second saddle 706, 708 which are used to receive and spread the load from the upper and lower spinous processes. The saddle 706 is defined by first and second arms 710 and 712. The second saddle 708 is defined by third and fourth arms 714 and 716. As can be seen in Fig. 74, the first arm 710, in a preferred

embodiment, is approximately two times the length of the body 702 with the second arm being approximately less than a quarter length of the body. Third arm 714 is approximately one times the length of the body 702 with the fourth arm 716 being, in this preferred embodiment, approximately one and a half times the length of the body 702. The arms are designed in such a way that the implant (1) can be easily and conveniently inserted between the adjacent spinous processes, (2) will not migrate forwardly toward the spinal canal, and (3) will hold its position through flexion and extension as well as lateral bending of the spinal column.

First arm 710 is in addition designed to accommodate the shape of the vertebra. As can be seen in Fig. 74, the first arm 710 becomes narrower as it extends away from the body 702. The first arm 710 includes a sloping portion 718 followed by a small recess 720 ending in a rounded portion 722 adjacent to the end 724. This design is provided to accommodate the anatomical form of for example the L4 vertebra. It is to be understood that these vertebra have a number of surfaces at roughly 30° angles and that the sloping surfaces of this embodiment and the embodiments shown in Figs. 77 and 78 are designed to accommodate these surfaces. These embodiments can be further modified in order to accommodate other angles and shapes.

The second arm 712 is small so that it is easy to insert between the spinous processes, yet still define the saddle 706. The fourth arm 716 is larger than the third arm 714, both of which are smaller than the first arm 710. The third and fourth arms are designed so that they define the saddle 706, guide the spinous processes relative to the implant 700 during movement of the spinal column, and yet are of a size which makes the implant easy to position between the spinous processes.

5 The procedure, by way of example only, for implanting the
implant 700 can be to make an incision laterally between two spinous
processes and then initially insert first arm 710 between the spinous
processes. The implant and/or appropriate tools would be used to
distract the spinous processes allowing the third leg 714 and the central
body 702 to fit through the space between the spinous processes. The
third leg 714 would then come to rest adjacent the lower spinous
processes on the opposite side with the spinous processes resting in the
first and second saddle 706, 708. The longer fourth leg 716 would
10 then assist in the positioning of the implant 700.

15 Fig. 77 includes an implant 740 which is similar to implant 700
and thus have similar numbering. The saddle 706, 708 of implant 740
have been cantered or sloped in order to accommodate the bone
structure between, by way of example, the L4-L5 and the L5-S1
vertebra. As indicated above, the vertebra in this area have a number
of sloping surfaces in the range of about 30°. Accordingly, saddle 706
is sloped at less than 30° and preferably about 20° while saddle 708 is
sloped at about 30° and preferably more than 30°.

20 The implant 760 as shown in Fig. 78 is similar to implant 700 in
Fig. 74 and is similarly numbered. Implant 760 includes third and fourth
legs 714, 716 which have sloping portions 762, 764 which slope
toward ends 766, 768 of third and fourth arm 714, 716 respectively.
The sloping portions accommodate the form of the lower vertebra
against which they are positioned. In the preferred embodiment, the
25 sloping portions are of about 30°. However, it is to be understood that
sloping portions which are substantially greater and substantially less
than 30° can be included and be within the spirit and scope of the
invention.

Industrial Applicability

From the above, it is evident that the present invention can be used to relieve pain caused by spinal stenosis in the form of, by way of example only, central canal stenosis or foraminal (lateral) stenosis. These implants have the ability to flatten the natural curvature of the spine and open the neural foramen and the spacing between adjacent vertebra to relieve problems associated with the above-mentioned lateral and central stenosis. Additionally, the invention can be used to relieve pain associated with facet arthropathy. The present invention is minimally invasive and can be used on an outpatient basis.

Additional aspects, objects and advantages of the invention can be obtained through a review of the appendant claims and figures.

It is to be understood that other embodiments can be fabricated and come within the spirit and scope of the claims.